

CLAIMS:

1. A method of providing information on DNA samples, the method including:-
 - in respect of one or more negative controls, obtaining information on whether or not DNA is suggested as present in the negative controls;
 - 5 determining the probability of DNA being suggested as present in the negative controls, the determination being based on the number of the negative controls which suggest DNA is present compared with the total number of negative controls considered; the probability of DNA being indicated as present in the negative control being equated to the probability of the DNA samples being contaminated.
- 10 2. A method of analysing DNA samples, preferably according to claim 1, in which the method including the analysis of negative controls to provide information on the contamination of DNA samples, wherein, in respect of at least one sample, a negative control arises at the point of the DNA samples collection and is treated in the same manner between that point and the conclusion of the analysis method.
- 15 3. A method of operating a database containing information on DNA from samples, the method of operating including:-
 - introducing into the database results from one or more sources;
 - the operator of the database specifying to the sources that the sources collect information according to a method for providing information on DNA samples, that
- 20 20 method including:-
 - in respect of one or more negative controls, obtaining information on whether or not DNA is suggested as present in the negative controls;
 - determining the probability of DNA being suggested as present in the negative controls, the determination being based on the number of the negative controls which suggest DNA is present compared with the total number of negative controls considered;
 - 25 the probability of DNA being indicated as present in the negative control being equated to the probability of the DNA samples being contaminated.

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4. A method according to any preceding claim in which the contamination is due to persons involved in the collection and/or handling and/or analysis of the sample and / or the reagents involved in the collection and/or handling and/or analysis of the sample and / or the equipment involved in the collection and/or handling and/or analysis of the sample.

5 5. A method according to any preceding claim in which the one or more negative controls pass through the stages of the process they are to provide information for in an equivalent manner to the samples as they pass through those stages of the process.

10 6. A method according to any preceding claim in which the information on the contamination of DNA samples is provided in respect of a period of time and after the elapse of the time period the method is repeated.

7. A method according to any preceding claim in which after a change in one or more of elements of the method, the method is repeated and the repeat of the method may provide revised information.

15 8. A method according to any preceding claim in which the determination of the probability of DNA being indicated as present in the negative control is the number of negative controls which suggest DNA is present divided by the total number of negative controls.

20 9. A method according to any preceding claim in which with respect to a sample, the method further provides a determination of the probability of a sample suggesting DNA is present in the sample, but that DNA arises from contamination only.

25 10. A method according to claim 9 in which the determination involves, in respect of one or more samples, obtaining information on whether or not DNA is suggested as present in the sample, the number of samples not suggesting DNA is present compared with the total number of samples considered is assumed to determine the probability of a sample not suggesting DNA as present, the probability of a sample not suggesting DNA as present is multiplied by the probability of a negative control being contaminated to give the

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probability of a sample suggesting DNA is present in the sample, but that DNA arises from contamination only.

11. A method according to any preceding claim in which with respect to a sample, the method further provides a determination of the probability of a sample suggesting DNA is present in the sample, the DNA arising from the sample and from contamination.

12. A method according to claim 11 in which the determination involves, in respect of one or more samples, obtaining information on whether or not DNA is suggested as present in the sample, the number of samples not suggesting DNA is present compared with the total number of samples considered is assumed to determine the probability of a sample not suggesting DNA as present, the probability of a sample not suggesting DNA as present is multiplied by the probability of a negative control being contaminated to give the probability of a sample suggesting DNA is present in the sample, but that DNA arises from contamination only, the determination further involving subtracting the probability of a sample suggesting DNA is present, but that DNA arises from contamination only, from the probability of a negative control being contaminated.

13. A method according to any preceding claim in which the method is applied to one or more groups of samples and/or negative controls.

14. A method according to claim 13 in which a group is the samples and negative controls from one operating organisation and / or a group is the samples and negative controls from one processing line of an operating organisation.

15. A method according to any preceding claim in which the information from the method is provided to one or more of the subsequent users of the DNA profile or results underlying it, together with the DNA profile or results underlying it, for instance the provider of a database of profiles from known persons and/or from known items or locations and/or from unknown persons.

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16. A method according to any preceding claim in which the information is used to assist in defining the format, for instance protocol, followed in a DNA sample analysis process, the DNA sample analysis process using two or more protocols dependent on one or more variables detected.

5 17. A method according to claim 16 in which the or one of the variables are the peak height and/or peak area detected for a sample and/or negative control and where a peak height and/or peak area is detected above a threshold a first protocol are used in the analysis and where a peak height and/or peak area is detected at or below a threshold a second protocol is used.

10 18. A method according to claim 17 in which the information of the present method is used to determine whether or not the threshold is set at an appropriate level and / or to determine the appropriate level for the threshold.

19. A method according to any preceding claim in which the method includes simulating sample DNA and contamination DNA in combination.

15 20. A method according to claim 19 in which each simulated mixture possible, formed of one negative control from amongst the one or more negative controls and one sample from amongst the one or more samples, is simulated.

20 21. A method according to claim 19 or claim 20 in which the simulation includes information on the quantity of DNA present in the simulated mixture due to the sample and due to the negative control and / or the simulation includes information on the peak area and/or peak height for DNA present in the simulated mixture due to the sample and due to the negative control.

25 22. A method of providing information on possible errors in a method of analysis, the method of analysis including a threshold which determines the analysis protocol to be applied to the analysis of DNA, the method including:-

in respect of one or more negative controls, obtaining information on whether or not DNA is suggested as present in the negative controls;

determining the probability of DNA being suggested as present in the negative controls, the determination being based on the number of the negative controls which suggest DNA is present compared with the total number of negative controls considered;

the probability of DNA being indicated as present in the negative control being equated to the probability of the DNA samples being contaminated;

in respect of one or more DNA samples, obtaining information on whether or not DNA is suggested as present in the DNA sample;

obtaining information about the quantity of DNA in a DNA sample or negative control;

comparing the quantity of DNA in a negative control sample with the threshold to establish the number or proportion of negative controls on one or other side of the threshold.

15 23. A method according to claim 22 in which the method includes adjusting the level of the threshold to alter the number or proportion of negative controls on one or other side of the threshold and / or the method includes adjusting the level of the threshold to reduce the number or proportion of negative controls above the threshold.

20 24. A method of providing information on, in a method of analysis, the likelihood of a result arising due to contamination, the method of analysis including a threshold which determines the analysis protocol to be applied to the analysis of DNA, the method of providing information including:-

in respect of one or more negative controls, obtaining information on whether or not DNA is suggested as present in the negative controls;

determining the probability of DNA being suggested as present in the negative controls, the determination being based on the number of the negative controls which suggest DNA is present compared with the total number of negative controls considered;

the probability of DNA being indicated as present in the negative control being equated to the probability of the DNA samples being contaminated;

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in respect of one or more DNA samples, obtaining information on whether or not DNA is suggested as present in the DNA sample;

obtaining information about the quantity of DNA in a DNA sample or negative control;

5 simulating one or more mixtures, the mixtures each being formed from a pairing of a negative control sample and a DNA sample from amongst the one or more negative controls and the one or more DNA samples;

10 establishing the mixture proportion for one or both of the following types of simulated mixture: DNA from contamination only; DNA from both DNA sample and contamination;

determining a likelihood ratio in respect of a result arising for one or both of the types of simulated mixture.

25. A method according to claim 24 in which the information on possible errors is an indication as to the number of negative controls which contain a quantity of DNA above 15 the threshold and / or the information on possible errors is an indication as to the number of contaminated samples which contain DNA above the threshold.

26. A method according to claim 24 or claim 25 in which samples above or at and above the threshold are subjected to a first protocol and / or samples at and below or below the threshold are subjected to a second protocol.

20 27. A method according to any of claims 24 to 26 in which a probability of achieving a given likelihood ratio is determined and such a determination is made in respect of one or more likelihood ratio levels and/or is made in respect of one or more threshold values.

25 28. A method according to any claim depending from claim 26 in which the method includes varying the threshold to give a predetermined likelihood ratio and/or predetermined probability of achieving a likelihood ratio.

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29. A method according to any of claims 24 to 26 in which the method is applied independently to different operating organisations and/or different processing lines within organisations.

5 30. A method, particularly according to claim 3, in which the sources are one or more operating organisations.

31. A method, particularly according to claim 3 in which the information on DNA samples is reviewed by the database operator, the database operator uses the information to specify the threshold at which the source uses one or more protocols in their analysis.

10 32. A method according to claim 31 in which the database operator specifies a threshold below which the source needs to use a particular protocol, such as a low copy number protocol.

33. A method according to claim 31 or claim 32 in which the database operator varies the threshold from time to time.

15 34. A method of providing information on the contamination of DNA samples by persons involved in the processing of DNA samples, the method including:-
determining DNA information of the same type as being analysed for in respect of one or more of the persons involved in processing the DNA samples;
determining the number of samples and/or negative controls contaminated by the one or more persons for whom the DNA information has been determined due to the
20 detection of DNA information corresponding to their DNA information in samples and/or negative controls;

determining the proportion of samples and/or negative controls handled by such persons;

25 determining the proportion of persons for whom the DNA information has been determined compared with the total number of persons involved in processing the DNA samples.

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35. A method according to claim 34 in which the proportion of samples and/or negative controls contaminated is divided by the proportion of persons for whom the DNA information has been determined to give the total proportion of samples and/or negative controls contaminated by the total number of persons involved in the processing of the DNA samples.

36. A method of determining the threshold to be used within a method of analysis by an operating organisation to determine which analysis protocol to apply, the method including:-

- setting a threshold;
- 10 determining the likelihood ratio for false positives for that operating organisation with that threshold;
- adjusting the value of the threshold ensure false positives do not exceed a desired likelihood ratio.